Commonwealth of Virginia
Department of Environmental Quality
Division of Water Quality
Ellen Gilinsky, Ph.D., Director

SUBJECT: Guidance Memo No. 04-2019
Revised Commercial Laboratory Inspection Procedures

TO: Regional Directors

FROM: Ellen Gilinsky, Ph.D. Director

DATE: October 27, 2004

COPIES: Regional Compliance Enforcement Managers, Regional Compliance Managers, Regional Permit Managers, Jon van Soestbergen, Bill Purcell, Amy Owens, Kathleen O'Connell, Betsy Ziomek

Summary:
This guidance is provided to the Central Office and Regional Office water compliance staffs concerning the procedures for conducting inspections of commercial laboratories that perform analyses for VPDES/VPA permit holders. These procedures are intended to make inspection of commercial laboratories mirror as closely as possible the procedures currently employed when inspecting permittee operated laboratories and to keep permittees informed regarding the status of the commercial laboratories they use.

Electronic Copy:
An electronic copy of this guidance in PDF format is available for staff internally on DEQNET, and for the general public on DEQ's website at http://www.deq.virginia.gov.

Contact Information:
Contact Bill Purcell, Water Inspections Coordinator at 804-698-4048 with any questions about the application of this guidance.

Disclaimer:
This document is provided as guidance and, as such, sets forth standard operating procedures for the agency. It does not establish or effect legal rights or obligations. It does not establish a binding norm and is not finally determinative of the issues addressed. Agency decisions in any particular case will be made by applying the State Water Control Law and the implementation regulations on the basis of site specific facts.

Commercial Laboratory Inspection

1.0 Scheduling

Major commercial laboratories should be inspected annually and minor commercial laboratories should be inspected every other year. A major commercial laboratory is any laboratory that does permit related analyses for any VPDES major facility or has 10 or more VPDES/VPA clients. Minor laboratories are those that serve fewer than 10 VPDES/VPA clients. Inspections should be unannounced and scheduled randomly each year. Conducting unannounced inspections is an agency goal. An inspection can be announced only if there is sufficient justification for such action. Announcing an inspection for the convenience of the laboratory or inspector is not sufficient justification. Some commercial laboratories are associated with the military installations. Security considerations at these laboratories necessitate announced inspections. Specific questions about what would be sufficient justification for an announced inspection can be directed to the Inspections Coordinator in the central office. The justification for an announced inspection must be included in the regional office inspection file.

2.0 Pre-inspection Activity

DEQ inspects commercial laboratories to validate work for VPDES/VPA clients; therefore inspectors must develop a list of permittees and respective analytes for evaluation. It is not necessary to develop an all-inclusive list but the list should prioritize majors and significant minors. During the entrance interview inspectors can ask laboratory management for a list of their VPDES/VPA clients. Most laboratories will provide a list of their permitted clients and the list can be used as a basis for the inspection. If the commercial laboratory cannot or will not provide a list, the inspector-generated list will be the basis for the laboratory audit.

A client/parameter list can be generated by reviewing:

- Certificates of analysis (COA) submitted to the agency
- Past laboratory inspection reports
- DMRQA results

The DMRQA coordinator provides the regional offices with an Excel spreadsheet each year that contains the contract laboratories used by all major VPDES dischargers and selected minors. The parameters performed by each laboratory can be found on the hardcopy DMRQA report. To facilitate generation of client lists, a computer based tracking system will be developed prior to June 30, 2005 by the user group based on existing tracking systems that contains the pertinent information. It is anticipated that DMR's will be modified to contain commercial laboratory information. Prior to the DMR being changed the tracking database can be populated with information gathered from the sources listed above.

3.0 Right of Entry

DEQ's authority to enter and inspect commercial laboratories under the authority of VPDES and VPA permits is clear. VPDES and VPA permits state that DEQ may:

> "*Enter upon the permittee's premises where a regulated facility or activity is located or conducted, or where records must be kept under the conditions of this permit;*
>
> *Have access to copy, at reasonable times, any records that must be kept under the conditions of this permit;*
>
> *Inspect at reasonable times any facilities, equipment (including monitoring and control equipment), practices, and or operations regulated or required under this permit*;"

Guidance issued from the Office of the Attorney General on June 8, 2000 confirms that inspection staff does have authority to enter and inspect commercial laboratories that are performing permit-related analyses. If an inspector is refused access to a commercial laboratory they are to ask why and attempt to gain access through negotiation. Under no circumstance is the inspector to do or say anything that can be construed to be hostile or threatening if refused access to the laboratory. Negotiations should be conducted in a firm but professional manner. If negotiations fail, make sure that the laboratory management understands that warning letters will be sent to their clients explaining that analytical results from their commercial laboratory will not be accepted for permit compliance because access to their records was denied. If permission to conduct an inspection is withdrawn during an inspection, follow the procedures outlined above. Do not relinquish any information gathered up to that point.

Denial of entry is more than being barred from entering the laboratory. An unreasonable condition placed on the inspector that prevents them from conducting an inspection as they normally would is to be considered denial of entry. This includes, but is not limited to, being prevented from interviewing analysts, viewing demonstrations of analytical procedures and examining instrumentation. Additionally, abusive and or hostile actions toward inspectors are considered denial of entry. If an inspector feels threatened the inspection should be terminated and regional and central office management should be consulted.

As photographs of laboratory equipment and conditions are an effective means of documentation inspectors should take digital cameras on inspections.. The inspector must inform the site representative that he or she will be taking photographs as a routine part of their inspection. If the facility representative expresses reservations about allowing the inspector to take photographs, these concerns should be discussed to seek a mutually acceptable solution. This can be as simple as agreeing to avoid photographing sensitive items which are irrelevant to the inspection, and/or allowing the representative to look through the camera's viewfinder prior to taking the photograph. With digital and

video photography it is possible to immediately show the representative your image with the option to delete it if deemed unacceptable. As a general rule, it is considered a denial of entry when a facility imposes any photographic restrictions that limit the inspector from properly performing the inspection. The Federal Water Pollution Control Act (FWPCA) gives the inspector the authority to collect and copy records including photographic images during an inspection. During special circumstances such as Confidential Business Information (CBI) claims, the inspector may take the photographs, but he/she must handle the photographs following all CBI procedures. If a claim of confidentiality is asserted, the information will be treated in accordance with the procedures in the Virginia Freedom of Information Act (§§ 2.1-340 et seq. and 62.1-44.21 of the Code of Virginia). If there are other circumstances such as national security issues, the inspector should try to collect the evidence needed without taking photographs.

4.0 Entrance Interview

During introductions before the entrance interview, exchange business cards and present credentials. The entrance interview is the inspector's opportunity to set a professional tone for the inspection and to facilitate an open exchange of information. The following are the key elements of an entrance interview:

1. Present the Requested Documentation List (Attachment I). Review the list of documents to be photocopied and explain how the inspection will be conducted and the objectives of the inspection. (Note: Attachment I can be modified to meet the objectives of the inspection.)
2. Discuss any VPDES/VPA testing subcontracted out to other commercial laboratories.
3. Explain to the laboratory management that if deficiencies are identified during, or subsequent to the inspection, and if corrective action is not implemented within 15 days of receipt of the inspection report, warning letters and summaries will be sent to affected clients.
4. Answer any questions the laboratory staff might have regarding the inspection.

If entry to the laboratory is denied, tactfully attempt to determine the reason. Explain that if the inspection cannot be completed warning letters (Attachment II) will be sent to the VPDES/VPA clients listed.

5.0 Onsite Evaluation

Inspection of a commercial laboratory is no different than inspection of a permittee operated laboratory except that a commercial laboratory will have a sample receiving area and a greater volume and variety of parameters analyzed. Due to the size of some laboratories it is advisable to conduct inspections with teams of inspectors to avoid lengthy stays. Having multiple inspectors present for an inspection may also provide corroborative testimony. Conduct inspections in an orderly fashion and whenever possible observe analysts running samples. If this is not possible, ask the analyst to walk through the analytical procedure. The practice of simply reading the checksheet

questions is to be avoided because having the analyst respond "yes" to a list of questions is not very informative. While onsite, review original benchsheets for white outs and other notations that do not translate well on photocopies. A more detailed examination can be conducted of the photocopied documentation back at the office. Inspections are particularly stressful for the bench chemist since they potentially have their supervisor and a DEQ inspector looking over their shoulder. Keep this in mind when interviewing analysts. Use the checksheets as a guide to evaluate the procedures observed during the inspection.

When evaluating the sample receiving area make sure sample preservations are checked and recorded upon sample receipt. Samples are to be stored in a limited access area, free from potential contamination and at the proper temperature. Sample containers are to be clearly labeled with unique sample identification. It is recommended that any preservative added to the sample container be written on the label. The chain of custody (COC) will list the analyses to be run from each sample container. Review necessary documents to insure that holding times are being met. Note whether field activities such as field filtration of dissolved metals samples are documented on the chain of custody form.

Do not discuss with laboratory personnel any potential criminal activities (e.g. dry labbing, falsification, sample tampering) discovered during the audit. Discretely collect supporting evidence and complete the audit normally. Discuss findings with appropriate regional and central office staff.

6.0 Exit Interview

Following completion of the inspection, discuss the findings, including any deficiencies noted, with laboratory management. Encourage laboratory management to allow bench chemists to participate in the debriefing. Stress that corrective actions implemented before the inspection report is prepared and mailed will be reflected in the report. Clarify that more deficiencies may be found during the data audit phase of the inspection and that these deficiencies will also be reflected in the final inspection report. Make sure any questions the laboratory staff has are answered before leaving.

7.0 Laboratory Inspection – No Deficiencies

Compile the inspection report and mail to the commercial laboratory within 30 days of the site visit.

8.0 Laboratory Inspection - Deficiency Found

Compile the inspection report, incorporating any corrective action taken by the laboratory, and transmit via certified mail to the laboratory within 30 days of the site visit. The report cover letter will state that warning letters will be sent to clients impacted by uncorrected deficiencies if corrective action is not implemented within 15 days after receipt of the inspection report and will continue to be sent each month that deficiencies

remain uncorrected. If uncorrected deficiencies remain or if no response is received from the commercial laboratory within the required deadline, warning letters and copies of the laboratory inspection report summary will be sent to all clients affected. Warning letters will state that warning letters will continue to be sent each month that deficiencies remain until there are sufficient points for the issuance of an NOV. Clients of the laboratory who are not directly affected by the deficiencies will not be contacted. For laboratories with clients located in multiple regions, the region conducting the inspection will forward the client list and the pertinent information to the appropriate region for mailing. If deficiencies are corrected within the 15 day deadline send the commercial laboratory a letter confirming the corrective actions. Re-inspection to verify corrective actions is at the discretion of the regional office. Re-inspection should be conducted as soon as practicable to quickly resolve any questions.

Attachment I

Requested Documentation

Please provide photocopies of the following documents as applicable.

- Client List – Please include all VPDES/VPA permitted facilities that contract with you for sample analysis and the parameters involved. Include any parameters that are subcontracted out to other laboratories. This list should reflect clients served in the previous 12 months.

- Chain of Custody and Certificate of Analysis for VPDES/VPA Clients - Please provide COAs and COCs for all VPDES/VPA clients for _____ 20XX.

- Calibration and Certification - Please provide the most recent calibration documentation for auto-pipettes, thermometers/thermistors and analytical balances and certification for NIST traceable thermometers and Class I weights.

- Analytical Benchsheets – Please provide analytical benchsheets for the specified VPDES/VPA permittees for _____ 20XX. Include any supporting information such as calibration curves that are necessary to calculate a result.

- Temperature Logs - Please provide the temperature logs for ovens, incubators, sample storage refrigerators, and autoclaves for _____ 20XX.

- QC/QA - Please provide blanks, duplicates, spike, digestion logs and standards performed for VPDES/VPA compliance if not included on the individual benchsheets for _____ 20XX. In addition, please include the most recent bacteriological water quality information (e.g. water quality test, TOC, pH, heavy metals)

Attachment II

[DATE]

[ADDRESS]

WARNING LETTER

Re: [Facility Name]
VPDES Permit No. VA

Dear Mr./Mrs.:

This letter is to notify you that on [inspection date], the Department of Environmental Quality (DEQ) attempted to perform a routine inspection of [commercial laboratory name] in [laboratory location] for the purpose of evaluating data and lab procedures for VPDES Permit-required analyses for [facility name]. DEQ staff were denied access to [laboratory name] for the purposes of reviewing how the VPDES analytical data you submit is determined and whether the data meets all the requirements of your permit.

Denial of entry calls into question the validity of data provided by the [facility name] on its Discharge Monitoring Report (DMR). Section _____of the Permit requires that certain lab testing procedures be followed in the analysis of the [facility name] wastewater discharge. If the [facility name] or your contract laboratory cannot demonstrate that the Permit's testing requirements are being met then DEQ cannot confirm the validity of your DMR data. This is considered to be a serious situation by DEQ because the reliability of permittee self-monitoring is the cornerstone of the VPDES program. By conducting inspections of commercial laboratories DEQ can identify deficiencies that affect the information provided by permittees on their DMRs.

DEQ requests a response from you within thirty days regarding your proposed action to address this situation and the timeframe in which the problem is expected to be resolved. You may wish to contact [commercial laboratory] to discuss the situation. Be advised that failure to respond to this correspondence, within thirty days, may result in enforcement action being taken in this matter.

This Warning Letter is not an agency proceeding or determination that may be considered a case decision under the Virginia Administrative Process Act, Va. Code §2.2-4000. Your contact for this matter at DEQ is**_____at ( ) .** Please contact him/her if you have any questions about the content of this letter or need additional guidance.

Sincerely,

[Water Compliance Manager]

Commercial Laboratory Inspection Flowchart